

reports on any of the events specified in § 1311.215 in a format that is readable by the pharmacist. Such an internal audit may be automated and need not require human intervention to be conducted.

(16) The pharmacy application must protect the stored audit records from unauthorized deletion. The pharmacy application shall prevent modifications to the audit records.

(17) The pharmacy application must back up the controlled substance prescription records daily.

(18) The pharmacy application must retain all archived records electronically for at least two years from the date of their receipt or creation and comply with all other requirements of § 1311.305.

#### **§ 1311.210 Archiving the initial record.**

(a) Except as provided in paragraph (c) of this section, a copy of each electronic controlled substance prescription record that a pharmacy receives must be digitally signed by one of the following:

(1) The last intermediary transmitting the record to the pharmacy must digitally sign the prescription immediately prior to transmission to the pharmacy.

(2) The first pharmacy application that receives the electronic prescription must digitally sign the prescription immediately on receipt.

(b) If the last intermediary digitally signs the record, it must forward the digitally signed copy to the pharmacy.

(c) If a pharmacy receives a digitally signed prescription that includes the individual practitioner's digital signature, the pharmacy application must do the following:

(1) Verify the digital signature as provided in FIPS 186-3, as incorporated by reference in § 1311.08.

(2) Check the validity of the certificate holder's digital certificate by checking the certificate revocation list. The pharmacy may cache the CRL until it expires.

(3) Archive the digitally signed record. The pharmacy record must retain an indication that the prescription was verified upon receipt. No additional digital signature is required.

#### **§ 1311.215 Internal audit trail.**

(a) The pharmacy application provider must establish and implement a list of auditable events. The auditable events must, at a minimum, include the following:

(1) Attempted unauthorized access to the pharmacy application, or successful unauthorized access to the pharmacy application where the determination of such is feasible.

(2) Attempted or successful unauthorized modification or destruction of any information or records required by this part, or successful unauthorized modification or destruction of any information or records required by this part where the determination of such is feasible.

(3) Interference with application operations of the pharmacy application.

(4) Any setting of or change to logical access controls related to the dispensing of controlled substance prescriptions.

(5) Attempted or successful interference with audit trail functions.

(6) For application service providers, attempted or successful annotation, alteration, or destruction of controlled substance prescriptions or logical access controls related to controlled substance prescriptions by any agent or employee of the application service provider.

(b) The pharmacy application must analyze the audit trail at least once every calendar day and generate an incident report that identifies each auditable event.

(c) The pharmacy must determine whether any identified auditable event represents a security incident that compromised or could have compromised the integrity of the prescription records. Any such incidents must be reported to the pharmacy application service provider, if applicable, and the Administration within one business day.

#### **§ 1311.300 Application provider requirements—Third-party audits or certifications.**

(a) Except as provided in paragraph (e) of this section, the application provider of an electronic prescription application or a pharmacy application must have a third-party audit of the

application that determines that the application meets the requirements of this part at each of the following times:

(1) Before the application may be used to create, sign, transmit, or process controlled substance prescriptions.

(2) Whenever a functionality related to controlled substance prescription requirements is altered or every two years, whichever occurs first.

(b) The third-party audit must be conducted by one of the following:

(1) A person qualified to conduct a SysTrust, WebTrust, or SAS 70 audit.

(2) A Certified Information System Auditor who performs compliance audits as a regular ongoing business activity.

(c) An audit for installed applications must address processing integrity and determine that the application meets the requirements of this part.

(d) An audit for application service providers must address processing integrity and physical security and determine that the application meets the requirements of this part.

(e) If a certifying organization whose certification process has been approved by DEA verifies and certifies that an electronic prescription or pharmacy application meets the requirements of this part, certification by that organization may be used as an alternative to the audit requirements of paragraphs (b) through (d) of this section, provided that the certification that determines that the application meets the requirements of this part occurs at each of the following times:

(1) Before the application may be used to create, sign, transmit, or process controlled substance prescriptions.

(2) Whenever a functionality related to controlled substance prescription requirements is altered or every two years, whichever occurs first.

(f) The application provider must make the audit or certification report available to any practitioner or pharmacy that uses the application or is considering use of the application. The electronic prescription or pharmacy application provider must retain the most recent audit or certification results and retain the results of any other audits or certifications of the ap-

plication completed within the previous two years.

(g) Except as provided in paragraphs (h) and (i) of this section, if the third-party auditor or certification organization finds that the application does not meet one or more of the requirements of this part, the application must not be used to create, sign, transmit, or process electronic controlled substance prescriptions. The application provider must notify registrants within five business days of the issuance of the audit or certification report that they should not use the application for controlled substance prescriptions. The application provider must also notify the Administration of the adverse audit or certification report and provide the report to the Administration within one business day of issuance.

(h) For electronic prescription applications, the third-party auditor or certification organization must make the following determinations:

(1) If the information required in §1306.05(a) of this chapter, the indication that the prescription was signed as required by §1311.120(b)(17) or the digital signature created by the practitioner's private key, if transmitted, and the number of refills as required by §1306.22 of this chapter, cannot be consistently and accurately recorded, stored, and transmitted, the third-party auditor or certification organization must indicate that the application does not meet the requirements of this part.

(2) If other information required under this chapter cannot be consistently and accurately recorded, stored, and transmitted, the third-party auditor or certification organization must indicate that the application has failed to meet the requirements for the specific information and should not be used to create, sign, and transmit prescriptions that require the additional information.

(i) For pharmacy applications, the third-party auditor or certification organization must make the following determinations:

(1) If the information required in §1306.05(a) of this chapter, the indication that the prescription was signed as required by §1311.205(b)(6), and the number of refills as required by §1306.22

of this chapter, cannot be consistently and accurately imported, stored, and displayed, the third-party auditor or certification organization must indicate that the application does not meet the requirements of this part.

(2) If the pharmacy application accepts prescriptions with the practitioner's digital signature, the third-party auditor or certification organization must indicate that the application does not meet the requirements of this part if the application does not consistently and accurately import, store, and verify the digital signature.

(3) If other information required under this chapter cannot be consistently and accurately imported, stored, and displayed, the third-party auditor or certification organization must indicate that the application has failed to meet the requirements for the specific information and should not be used to process electronic prescriptions that require the additional information.

#### **§ 1311.302 Additional application provider requirements.**

(a) If an application provider identifies or is made aware of any issue with its application that make the application non-compliant with the requirements of this part, the application provider must notify practitioners or pharmacies that use the application as soon as feasible, but no later than five business days after discovery, that the application should not be used to issue or process electronic controlled substance prescriptions.

(b) When providing practitioners or pharmacies with updates to any issue that makes the application non-compliant with the requirements of this part, the application provider must indicate that the updates must be installed before the practitioner or pharmacy may use the application to issue or process electronic controlled substance prescriptions.

#### **§ 1311.305 Recordkeeping.**

(a) If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.

(b) Records required by this subpart must be maintained electronically for

two years from the date of their creation or receipt. This record retention requirement shall not pre-empt any longer period of retention which may be required now or in the future, by any other Federal or State law or regulation, applicable to practitioners, pharmacists, or pharmacies.

(c) Records regarding controlled substances prescriptions must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read.

(d) Records required by this part must be made available to the Administration upon request.

(e) If an application service provider ceases to provide an electronic prescription application or an electronic pharmacy application or if a registrant ceases to use an application service provider, the application service provider must transfer any records subject to this part to the registrant in a format that the registrant's applications are capable of retrieving, displaying, and printing in a readable format.

(f) If a registrant changes application providers, the registrant must ensure that any records subject to this part are migrated to the new application or are stored in a format that can be retrieved, displayed, and printed in a readable format.

(g) If a registrant transfers its electronic prescription files to another registrant, both registrants must ensure that the records are migrated to the new application or are stored in a format that can be retrieved, displayed, and printed in a readable format.

(h) Digitally signed prescription records must be transferred or migrated with the digital signature.

### **PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES**

#### **Sec.**

- 1312.01 Scope of part 1312.
- 1312.02 Definitions.

#### **IMPORTATION OF CONTROLLED SUBSTANCES**

- 1312.11 Requirement of authorization to import.
- 1312.12 Application for import permit.
- 1312.13 Issuance of import permit.